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IN THE
# Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, *Petitioner*,

*v.*

LEROY CARHART, ET AL., *Respondents*.

ALBERTO R. GONZALES, ATTORNEY GENERAL, *Petitioner*,

*v.*

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., ET AL., *Respondents*.

On Writs Of Certiorari To The United States Courts Of Appeals For The Eighth and Ninth Circuits

## BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

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## STATEMENT OF INTEREST[1]

The American College of Obstetricians and Gynecologists ("ACOG") is a non-profit educational and professional organization founded in 1951. ACOG is the leading professional association of physicians who specialize in the health care of women. Its more than 50,000 members represent approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States.

ACOG represents the vast majority of physicians affected by the Partial-Birth Abortion Ban Act of 2003 ("the Act"). Though their views on abortion differ, ACOG's members agree that their chief goal is to improve women's health by providing their patients with the safest possible care. As a result, ACOG opposes laws, such as the Act, that would expose patients to serious, unnecessary health risks.

## INTRODUCTION

ACOG has consistently opposed bans such as the Act because they endanger women's health. While the Act threatens a broad array of safe abortion procedures used after the first trimester of pregnancy, the Act would endanger women even if—as the Government sometimes asserts—it reached only dilation-and-evacuation procedures in which the physician removes the fetus intact ("intact D&Es").

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[1] No counsel for a party authored any portion of this brief, and no person other than *Amicus* and its counsel contributed any money to the preparation or submission of this brief. *See* Rule 37.6. Letters of consent to the filing of this brief have been lodged with the Clerk of the Court. *See* Rule 37.3.

In defending the Act, the Government repeats Congress's finding that an intact D&E is "never medically indicated to preserve the health of the mother." *See Carhart* Pet'r Br. 2; *PPFA* Pet'r Br. 2. This core premise is, however, medically incorrect. The safety advantages of intact D&E include fewer insertions of instruments into the uterus, reduced risk of perforation, reduced likelihood of retained fetal tissue, reduced blood loss, and shorter time of anesthesia exposure. These safety advantages are particularly significant for women who suffer from serious medical conditions.

The averted harms are not "marginal," as the Government asserts, and include massive hemorrhaging, serious infection, and subsequent infertility. Indeed, after considering the issue in depth, ACOG concluded that intact D&E procedures "may be the best or most appropriate . . . in a particular circumstance to save the life or preserve the health of a woman." *Carhart* J.A. 976 (1997 ACOG Statement of Policy).[2]

The medical advantages of D&Es involving intact removal are now widely acknowledged. As reflected by hearings before Congress and in the courts, the safety advantages of the intact variant are recognized by an array of skilled physicians with impeccable credentials and vast clinical experience. These safety advantages are confirmed by leading medical texts and peer-reviewed studies; the curricula of leading medical schools; and even some of the Act's supporters—including the Government's

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[2] "*Carhart* Pet. App." and "*PPFA* Pet. App." refer to the Appendices to the Petitions for Writs of Certiorari filed in *Carhart v. Gonzales* and *Planned Parenthood Federation of America, Inc. v. Gonzales*. "*Carhart* J.A." and "*PPFA* J.A." refer to the Joint Appendices for the two cases. "CA8 App." refers to the *Carhart* Plaintiffs' Appendix in the Court of Appeals. "S.A." refers to the Supplemental Appendix attached to this brief.

own witnesses. Indeed, as medical practice has evolved in the nine years since ACOG first formulated its policy on intact D&E, and in the six years since this Court decided *Stenberg*, the medical consensus about these safety advantages has grown.

Against this backdrop, the consequences of the Act's failure to include an exception for procedures necessary to protect a woman's health are clear. The Act prevents physicians from providing the care that is most likely to avoid potentially catastrophic health outcomes. It thus imposes a risk of increased harms on those women for whom intact D&E would be the safest option.

Moreover, the Act prohibits more than just intact D&Es. The Act's broad scope and vague terms would chill physicians from performing any second-trimester abortion. And the Act would hinder medical advancement by preventing physicians from using their clinical experience to develop safer procedures.

Like all physicians, ACOG's members must both "recognize responsibility to patients first and foremost" and "respect the law." Amer. Med. Ass'n, *Principles of Medical Ethics: Preamble* (June 2001).[3] Because the Act impermissibly forces physicians to choose between those two duties, the decisions of the Courts of Appeals should be affirmed.

## STATEMENT OF FACTS

Every time a physician performs an induced abortion or treats a patient experiencing a miscarriage, the goal is the same: to empty the uterus using the safest techniques for the woman. A physician uses the same techniques

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[3] *Available at* http://www.ama-assn.org/ama/pub/category/2512.html.

whether treating a miscarriage or inducing an abortion. Physicians have continuously improved their techniques, such that in the United States an induced abortion is "one of the safest [surgical] procedures in contemporary practice." David A. Grimes & Mitchell D. Creinin, *Induced Abortion: An Overview for Internists*, 149 Annals Internal Med. 620, 623 (2004). Indeed, an induced abortion is many times safer for a woman than continuing a pregnancy through to childbirth. *See, e.g.*, David A. Grimes, *Estimation of Pregnancy-Related Mortality Risk by Pregnancy Outcome, United States, 1991 to 1999*, 194 Am. J. Obstetrics & Gynecology 92, 92-93 (2006). But the risks of abortion increase as pregnancy advances. *See, e.g.*, Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 Obstetrics & Gynecology 729, 732 (2004).

## A. Abortion Procedures

### *1. First-Trimester*

Almost 90% of induced abortions are performed in the first trimester of pregnancy. *See* Lilo T. Strauss et al., Nat'l Ctr. for Chronic Disease Prevention, *Abortion Surveillance—United States, 2002*, Morbidity and Mortality Wkly. Rep. Surveillance Summaries, Nov. 25, 2005, at 1, 21 tbl. 6. The first trimester runs through the first 13 weeks of pregnancy, measured from the first day of the last menstrual period ("LMP") before the woman became pregnant.

The great majority of first-trimester abortions are performed using a method called vacuum aspiration (sometimes called suction curettage). *See id.* at 31 tbl. 18. In these procedures, the physician dilates the cervix and inserts a tube called a cannula through the vagina and cervix and into the uterus. Once the cannula is in the uterus, the physician uses suction to empty the uterus.

*See A Clinician's Guide to Medical and Surgical Abortion* 111-112 (Maureen Paul et al. eds., 1999) ("*Clinician's Guide*").

*2. Second Trimester*

**Dilation and Evacuation.** In the second trimester of pregnancy (approximately 13-26 weeks LMP), when vacuum aspiration is no longer effective, over 95% of induced abortions are performed using the method known as dilatation and evacuation ("D&E"). *See* Strauss et al., *supra*, at 31 tbl. 18. Although individual physicians' techniques may vary somewhat, physicians generally begin by dilating the cervix with dilators, which absorb moisture from the woman's cervix and thus widen the opening of the cervix. These dilators are inserted hours to days prior to the evacuation portion of the procedure. The amount of time required for adequate dilatation varies based on factors including the duration of the pregnancy and the number of prior vaginal deliveries. Some physicians also use medications to facilitate dilation. In some cases of miscarriage, the cervix dilates on its own before the physician sees the patient, eliminating the need to initiate dilation before evacuating the uterus.

After the cervix is sufficiently dilated, the patient returns to the physician for the evacuation procedure. *See* Phillip G. Stubblefield et al., *Methods for Induced Abortion*, 104 Obstetrics and Gynecology 174, 179-180 (2004). After suctioning out the amniotic fluid, the physician reaches through the dilated cervix, generally with a clamp or forceps; grasps the fetus with the instrument; and then pulls the fetal part grasped within the instrument out through the cervix and vaginal canal. *See Clinician's Guide*, *supra*, at 133-36. At this point, when the physician starts to withdraw the forceps from the woman's body, the fetus is usually intact. Often, especially earlier in the second trimester, disarticulation

(or dismemberment) occurs as the physician delivers the fetal part grasped in the instrument and pulls it through the opening of the cervix. The physician then reinserts the forceps, and repeats this step until all fetal material has been removed from the uterus. *See id.* The fetus dies sometime during the process of disarticulation.

Physicians try to minimize the number of times they insert instruments into the woman's uterus, and therefore attempt to remove as much of the fetus as possible each time they insert the instrument. In some D&Es, little or no disarticulation occurs, and the physician removes the fetus relatively intact. This reduces instrumentation and therefore reduces the risk of injury to the woman's uterus. Any D&E can result in relatively intact removal of the fetus.

However, as the pregnancy advances, the fetal skull will become too large to pass through the cervix—especially later in the second trimester. Hence, whether the D&E involves extensive disarticulation or relatively intact removal, the fetal skull usually must be compressed to allow it to pass through the cervix without injuring the woman. *See* Warren M. Hern, *Abortion Practice* 199-200 (1984). And in many D&Es, the physician extracts part of the fetus while it retains a heartbeat or other indicia of life, such as a pulsating umbilical cord.

Starting at approximately the mid-point of the second trimester, some physicians more routinely perform D&Es in which the fetus is removed intact (sometimes known as "intact D&E" or the "intact variant"). In one technique, the physician brings the fetus through the cervix intact in a breech position. If the head then lodges in the uterus, it must be compressed to complete the extraction. ACOG has referred to this procedure as intact dilatation and extraction. *See* ACOG Statement of Policy, Abortion

Policy (July 2004), *reprinted in* ACOG, *2006 Compendium of Selected Publications* 1059-61 (2006) (reaffirming Jan. 1997 and Sept. 2000 revisions). In another technique, the physician begins by compressing the skull of a fetus that is presenting head-down—while it is entirely within the uterus. Once the head will fit through the cervix, the physician removes the fetus intact.

Because greater dilation generally increases the likelihood of intact extraction, whether intact extraction will be possible in any given case often depends on how far the cervix has dilated. But physicians cannot predict in which cases they will be able to remove the fetus intact or relatively intact. In most cases, physicians perform dilation on all of their patients the same way and hope to achieve enough dilation to facilitate intact extraction.

**Induction.** Other than D&E, almost all other induced abortions after the first trimester are performed by the method known as induction. In an induction abortion, the physician induces pre-term labor with potent medications, the cervix dilates, and the fetus is generally expelled through the labor process. The procedure requires constant monitoring and must be performed in a hospital. An induction lasts anywhere from fewer than twelve hours to more than forty-eight hours.

Induction poses specific risks to women with certain medical conditions, and may be entirely contraindicated for others. For example, induction abortions are relatively or absolutely contraindicated for women who have had a previous hysterotomy or cesarean section with a classical (vertical) scar, because they can lead to uterine rupture, hemorrhage, and even death. *See* P. Boulout et al., *Late Vaginal Induced Abortion after a Previous Cesarean Birth: Potential for Uterine Rupture*, 36 Gynecologic & Obstetric Investigation 87, 88 (1993).

In some circumstances in which the induction results in a breech delivery, the fetal skull may be too large to fit through the partially dilated cervix. In such cases, the physician generally must compress the skull to complete the delivery and reduce the likelihood of serious injury to the woman. In the case of an incomplete or unsuccessful induction, the physician must complete the abortion using D&E techniques. *See* Stubblefield et al., *supra*, at 180-81; *Clinician's Guide, supra,* at 151.

**Abdominal Surgery.** In rare instances, physicians perform abortions via abdominal surgery: hysterectomy (removal of the uterus) or hysterotomy (essentially a pre-term cesarean section). *See Williams Obstetrics* 245 (F. Gary Cunningham et al. eds., 22d ed. 2005) ("*Williams Obstetrics 2005*"). These procedures entail far higher risks for the woman than do either D&E or induction. Compared to the type of incision used for term cesarean deliveries, the incision in the uterus used for a second trimester abortion by hysterotomy has a higher risk of rupture in subsequent pregnancies. Such a rupture in a subsequent pregnancy can cause hemorrhage, loss of the uterus, fetal death, and even the woman's death. And a hysterectomy eliminates a woman's ability to bear children in the future. *See* P. Diggory, *Hysterotomy and Hysterectomy as Abortion Techniques, in Abortion and Sterilization: Medical and Social Aspects* 317, 331 (Jane E. Hodgson ed., 1981).

### B. ACOG's Statement of Policy on Intact D&E

In October 1996, ACOG's Executive Board, the governing body that sets policy for the organization, embarked on an effort to develop a policy statement concerning the so-called "partial birth abortion" procedure. A task force convened by the Executive Board reviewed the medical facts surrounding the issue and

drafted a proposed policy statement. The task force consisted of practicing obstetrician-gynecologists, who were "carefully select[ed] . . . based on their expertise and viewpoint"—ACOG "chose" task force members from diverse backgrounds." *Carhart* Pet. App. 424a-25a. Members included, among others, specialists in treating high-risk pregnancies and physicians who regularly performed or oversaw abortions, including intact D&Es. *See id.* at 425a-26a. The task force also included at least one physician who opposed abortion. *See id.* at 425a.

The task force members reviewed materials sent to them in advance and then met over a two day period to review the background literature and discuss specific cases in which the intact variant of D&E might be employed. *See id.* at 426a-33a. As one task-force member testified, there were "multiple circumstances that an expert panel could identify at the time of the task force where [intact D&E] was clearly the best choice, including . . . where the other options led to a higher likelihood of death or recurrence of disease." *Carhart* J.A. 502 (Cain Dep. Test.); *PPFA* J.A. 859 (same). Therefore, the task force concluded that intact D&E could be the safest or most appropriate procedure for a given patient, and that the decision whether to choose such a procedure should be left to a woman and her physician. *See Carhart* Pet. App. 436a. The task force presented this conclusion to ACOG's Executive Board in a draft Statement of Policy.

The Executive Board includes, among others, nationally elected officers, and elected representatives from each of ACOG's nine geographic districts and one district made up of members of the Armed Forces. At the time that ACOG's Executive Board considered the draft Statement of Policy, there were 19 members. The Executive Board approved the draft Statement of Policy, but determined that it should explicitly state the task

force's conclusion that an intact D&E may be the best or most appropriate procedure under certain circumstances.

The Executive Board inserted that conclusion (emphasized below) into its final policy statement which states, in relevant part:

> A select panel convened by ACOG could identify no circumstances under which [intact D&X] . . . would be the *only* option to save the life or preserve the health of the woman. ***An intact D&X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor, in consultation with the patient, based on the woman's particular circumstances can make this decision.*** The potential exists that legislation prohibiting specific medical practices, such as intact D&X, may outlaw techniques that are critical to the lives and health of American women.

*Carhart* J.A. 975-976 (second emphasis added). Despite routine turnover of its membership, the ACOG Executive Board reaffirmed the Statement of Policy in September 2000 and again in July 2004. *See* ACOG Statement of Policy, *supra*.

## ARGUMENT

### I. INTACT D&E IS NECESSARY TO PREVENT SERIOUS HARM.

Over 95% of women terminating a pregnancy in the second trimester undergo a D&E procedure. *See* Strauss et al., *supra*, at 31 tbl. 18. Among D&E procedures, those

in which the fetus is delivered intact, or relatively intact, offer potentially significant safety advantages.

### A. Intact D&E Reduces The Risk of the Most Serious Complications of Non-intact D&E.

The intact approach reduces the risk of the most severe complications of D&Es involving dismemberment by minimizing instrumentation and reducing the chances of retained fetal tissue.

First, the intact variant of D&E "minimize[s] instrumentation within the uterine cavity." *Clinician's Guide, supra*, at 136. It thus "facilitates extraction and minimizes uterine or cervical injury from instruments or fetal bones." *Williams Obstetrics 2005, supra*, at 243.

Fewer instrument passes and fewer fetal-bone fragments means less risk of uterine perforation—the most serious and feared complication of D&E. "[A] perforation occurring with second-trimester D&E may lead to bowel injury and will likely require laparotomy [open abdominal surgery]." Stubblefield et al., *supra*, at 180. A perforation that reaches the uterine artery, which is engorged during pregnancy, may cause catastrophic hemorrhage. "Uterine perforations that involve injury to major blood vessels or other organs . . . require in-hospital surgical management." *Clinician's Guide, supra*, at 178. Some uterine perforations can also reach the gastrointestinal tract, risking contamination of the abdominal cavity with bacteria (peritonitis) or entry of bacteria into the blood stream (sepsis). By causing tissue and organ damage, including damage to the brain and

other vital organs, both hemorrhage and sepsis can have long term effects on the woman's health.[4]

Second, removing the fetus intact also eliminates the possibility that fetal tissue will be retained in the uterus, a cause of hemorrhage or infection in non-intact D&E procedures. *See* Stubblefield, et al., *supra*, at 180 ("[h]emorrhage during or after D&E can be caused by an incomplete procedure"); *Clinician's Guide, supra*, at 201 (retained fetal tissue can cause bleeding, infection of the uterus and fallopian tubes, and sepsis). Long-term complications of retained fetal tissue also include infertility.

Third, intact removal increases the physician's control over the procedure. Increased control minimizes the likelihood of complications that are present in other forms of D&E. For example, removing the fetus intact reduces the likelihood that the physician will have to locate the last piece of fetal tissue remaining in the uterus by grasping repeatedly with the forceps—a process that risks injuring the woman. *See* Hern, *supra*, at 194-95.

Finally, emerging study data, confirmed by clinical experience, suggests that intact removal is faster than other methods used at comparable stages of pregnancy. A recent study measured the procedure time for both the intact and non-intact variants. The women who received the intact variant were two weeks later in pregnancy, and

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[4] "Obstetric hemorrhage can be of a volume large enough to precipitate a state of generalized circulatory failure, resulting in . . . irreversible tissue damage." Am. Acad. of Pediatrics & ACOG, *Guidelines for Perinatal Care* 180 (5th ed. 2002). Lungs, kidneys, and the pituitary gland are particularly susceptible to damage from hemorrhagic shock during pregnancy. *See Critical Care Obstetrics* 555 (Gary A. Dildy et al. eds., 4th ed. 2004). Sepsis can result in lung, liver, and kidney failure, damage to the brain and other organs, and even death. *See id.* at 329-31; *Williams Obstetrics 2005, supra*, at 994-95.

thus were expected to require longer procedures. But the intact procedures performed on the later-term women took no longer than the non-intact procedures performed on the earlier-term women—that suggests that all things being equal, intact D&Es are quicker. *See* Stephen T. Chasen et al., *Dilation and Evacuation at ≥ 20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstetrics & Gynecology 1180, 1180-03 (2004). The shorter the procedure lasts, the less the blood loss, trauma, exposure to anesthesia, and risk of serious complications.

### B. Intact D&E Is Safest For Women With Certain Conditions.

Intact removal offers particularly significant benefits for women suffering from certain medical conditions that make the potential complications of non-intact D&E especially grave. Hemorrhage, infection, and prolonged surgical intervention present particular risks for women with chronic medical conditions such as bleeding disorders, heart disease, or compromised immune-systems. The intact variant is also significantly safer for women with certain pregnancy-related conditions.

#### *1. Intact D&E is Safest for Women with Placenta Previa and Accreta.*

For some women with placenta previa, the intact variant minimizes the chance of hemorrhage. In this condition, the placenta partially or entirely covers the cervical opening, creating a risk of excessive bleeding when the cervix is dilated. *See Emergency Medicine: Concepts and Clinical Practice* 2377 (Peter Rosen et al. eds., 1998); *Williams Obstetrics 2005*, *supra*, at 819-820. Bleeding occurs when the placenta separates from the cervix and the uterine wall, and the bleeding cannot be controlled until after the uterus is emptied. While a

woman with placenta previa will begin to bleed in any D&E procedure when the cervix is dilated, causing the placenta to begin to separate, intact removal minimizes the risk of excessive bleeding and hemorrhage by reducing instrumentation and manipulation near the bleeding placenta. *See Carhart* J.A. 523 (Broekhuizen Trial Test.); *PPFA* J.A. 266-267 (same); *Carhart* J.A. 888 (Westhoff Trial Test.). In addition, because the intact variant can be performed more quickly than the non-intact technique, the bleeding can be controlled sooner and the risk of excessive bleeding is lower. Induction is absolutely contraindicated in cases of placenta previa because the lengthy process of the labor and delivery would result in life-threatening hemorrhage.

The intact variant may also be safest for women suffering from placenta accreta. Women with placenta accreta, which occurs when the placenta abnormally invades the wall of the uterus, may benefit from a procedure that minimizes the use of instruments in the uterine cavity. Such a procedure is less likely to disrupt the placenta and cause life-threatening hemorrhage. *See PPFA* J.A. 511-514 (Chasen Trial Test.).

*2. Intact D&E is Safest for Women with Chorioamnionitis.*

Intact D&E reduces the risk of harm to a patient with chorioamnionitis, a bacterial infection of the fetal membranes. The infection spreads rapidly to the fetus, placenta, and uterine wall, and eventually spreads to other pelvic organs, resulting in peritonitis and sepsis.

Even in the early stages of this condition, antibiotics cannot effectively treat the condition unless the uterus is also emptied of the pregnancy tissue. Thus, because it allows the physician to remove the fetus more quickly, the intact variant allows physicians to treat the infection

earlier and prevent its spread. The intact variant's lower risk of uterine perforation likewise helps prevent the infection from spreading beyond the uterus. Indeed, intact removal is also preferable if the woman has other infections because, as ACOG's Dr. Cain testified, "any increase in instrumentation might increase the ability of the bacteria to enter the blood stream." *Carhart* J.A. 507; *PPFA* J.A.1110.

These advantages were recognized even by one of the Government's experts. Dr. Lockwood testified that intact D&E might be advantageous for women with chorioamnionitis because the infection may have thinned or damaged the uterus. See *Carhart* J.A. 424-25. Other witnesses agreed that in those circumstances, "an intact D&E would be the optimal way to empty the uterus," because it decreases the risk of cervical laceration and hemorrhage, which are among the most common complications of D&E. *Carhart* J.A. 711-13 (Frederiksen Trial Test.); *see also id.* at 768, 770-71 (Hammond Trial Test.); *id.* at 124-25 (Vibhakar Trial Test.) (induction abortion is contraindicated for a woman with chorioamnionitis).

*3. Intact D&E is Safest for Women with Certain Fetal Abnormalities.*

Intact D&E may also be the safest procedure for a woman whose fetus has certain abnormalities—such as severe hydrocephalus, a greatly enlarged head—that make extraction difficult. The intact variant allows a doctor to reduce the size of the abnormally large head before it passes through the cervix—thereby reducing the risk of injury to the cervix. *See Carhart* J.A. 595 (Chasen Trial Test.). As recognized by the AMA task force—whose members included the Government's expert Dr. Sprang—intact D&E may be preferred "when the fetus has been diagnosed with hydrocephaly or other anomalies

incompatible with life outside the womb." *PPFA* J.A. 670-671 (Sprang Trial Test.).

### C. The Safety Benefits of Intact D&E Are Significant.

The Government repeatedly and incorrectly asserts that the medical benefits of D&E involving intact removal are insignificant, and thus that the risks imposed by banning such procedures are "marginal." *See Carhart* Pet'r Br. iv, 10, 14, 37, 39, 40, 42; *PPFA* Pet'r Br. 10, 24, 27-29. This argument misunderstands how doctors evaluate risk. It is a significant safety advantage where a procedure reduces the risk of a potentially catastrophic complication. And a ban on that procedure correspondingly places patients at significant risk by depriving them of the treatment that is most likely to help them avoid a tragic outcome.

Likewise, though complications from the non-intact variant are (fortunately) rare, the Government "cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it." *Stenberg v. Carhart*, 530 U.S. 914, 934 (2000). Denying women access to a procedure that could reduce those infrequent disastrous outcomes—especially women faced with the medical conditions described above—subjects them to real increased risk of serious harm.

It is thus medically incorrect to dismiss, as the Government does, the safety advantages of the banned procedures as "marginal."

## II. A MEDICAL CONSENSUS RECOGNIZES THAT INTACT D&E OFFERS HEALTH BENEFITS.

The safety advantages of intact D&E are widely recognized—in medical texts, peer-reviewed studies, clinical practice, and even by some of the Government's own witnesses. This broad collection of medical authority contradicts the Government's claim that only a "minority of medical professionals" recognize that a ban on intact D&E would subject women to significant health risks. *Carhart* Pet'r Br. 9; *PPFA* Pet'r Br. 10. These safety advantages are even more widely accepted today than they were six years ago, when this Court decided *Stenberg*. And they were apparent in the record that Congress considered in passing the Act.

### A. Authoritative Texts and Peer-Reviewed Articles

The intact variant and its safety advantages are recognized in authoritative medical texts and articles in peer-reviewed journals. A leading textbook on abortion methods describes the intact variant and suggests that it is safer because it reduces the need for insertion of instruments into the uterus. *See Clinician's Guide, supra,* at 136-37; *see also* Phillip G. Stubblefield, *First and Second Trimester Abortion, in Gynecologic, Obstetric, and Related Surgery* 1033, 1043 (David H. Nichols & Daniel L. Clarke-Pearson eds., 2d ed. 2000) (confirming that intact D&E is a recognized variant of D&E). The year after this Court decided *Stenberg*, *Williams Obstetrics*, another authoritative text in the field, recognized that the intact D&E is a variant of the D&E procedure. *See Williams Obstetrics* 871 (F. Gary Cunningham et al. eds., 21st ed. 2001). In 2005, *Williams Obstetrics* observed that the intact variant "facilitates extraction and minimizes uterine or cervical

injury from instruments or fetal bones." *Williams Obstetrics 2005*, *supra*, at 243.

Articles in leading, peer-reviewed medical journals also describe the intact variant of D&E and confirm the benefits of this "further evolution" of the D&E technique. Stubblefield et al., *supra*, at 179. For instance, a peer-reviewed study published in 2004 by Dr. Stephen T. Chasen of Cornell University suggests that intact D&E is safer than its alternatives. Dr. Chasen compared women who underwent non-intact procedures with those who underwent relatively intact procedures. *See* Chasen et al, *supra*, at 1181. Though the overall complication rates in the two groups were comparable, all of the serious complications were suffered by women who underwent the non-intact variant. *See id.* at 1182.

Moreover, the patients in the intact group had been pregnant longer. *See id.* at 1183. As the Government's Dr. Lockwood testified, the patients with longer pregnancies would have been expected to suffer higher rates of more serious complications. *See Carhart* J.A. 435, 440. That the women in the intact D&E group did not suffer such higher rates of more serious complications suggests that the intact procedures were at least as safe as, and likely safer than, the non-intact alternative.

### B. Medical Schools

Since this Court decided *Stenberg*, even more leading medical schools have started to teach the intact method of D&E. Among the schools that now teach the intact variant are Columbia, Cornell, Yale, New York University, Northwestern, University of Pittsburgh, University of Pennsylvania, University of Rochester, and University of Chicago. This evidence flatly contradicts Congress's finding that "no medical schools . . . provide

instruction" in D&E with intact removal. *Carhart* Pet. App. 595a (Act § 2(14)(B)).

Even the Government's expert, Dr. Lockwood, testified that he intended to establish a program that would teach intact D&E at Yale, where he chairs the Department of Obstetrics and Gynecology. *See Carhart* J.A. 406-07 (Lockwood Trial Test.). Yale now teaches the intact variant.

### C. Medical Associations

The intact variant's safety advantages are also recognized by leading medical associations. ACOG's own position on the intact variant, as reflected in its 1997 Statement of Policy, reaffirmed most recently in July 2004, belies the Government's claim that only a small minority of physicians assert the safety advantages of intact removal in a D&E. ACOG, which represents more than 90% of all board-certified obstetricians and gynecologists practicing in the United States, has concluded that intact D&E "[m]ay be the best or most appropriate procedure to save the life or preserve the health of a woman." *Carhart* J.A. 976 (1997 ACOG Statement of Policy).[5]

That ACOG "could identify no circumstances under which this procedure . . . would be the *only* option to save the life or preserve the health of the woman," *see id.* at 975-976 (emphasis in original), is in no way inconsistent with the proposition that intact D&E may be medically necessary in some cases to avoid significant risks to the

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[5] *See also Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the House Subcomm. on the Constitution of the Comm. on the Judiciary*, 108th Cong. 197 (2003) (2002 ACOG statement) ("there are circumstances under which intact D&X would be the most appropriate and safest procedure to save the life or health of a woman").

woman. While other abortion techniques may be available to terminate a particular woman's pregnancy, the intact variant may be the *safest* method for that woman.

Other leading medical associations agree. The American Medical Women's Association has concluded that D&E with intact removal is "in some circumstances . . . the safest and most appropriate alternative available to save the life and health of the woman." *See Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the House Subcomm. on the Constitution of the Comm. on the Judiciary*, 108th Cong. 201 (2003) ("*2003 Hearing*"). The American Public Health Association takes a similar position. *See* 149 Cong. Rec. S12931 (daily ed. Oct. 21, 2003) (statement of Sen. Boxer).

### D. Congress's "Findings" Are Contradicted by Its Own Record and the Medical Evidence.

Despite this medical consensus and the inclusion of intact D&E within mainstream care, the Government argues that this Court must defer to Congress's "findings" that intact D&E is never medically necessary. After reviewing the medical evidence before Congress, ACOG agrees with the District Court in *Carhart* that "the congressional record disproves the Congressional Findings." *Carhart* Pet. App. 464a.

Congress claimed that the procedure is disfavored "particularly among physicians who routinely perform other abortion procedures." *Id.* at 590a (Act §2(2)). Precisely the opposite was true: The National Abortion Federation, Planned Parenthood, and ten physicians with recent surgical-abortion experience all described the safety advantages of an intact approach to D&E. For example, Dr. Anne R. Davis stated that "there is no

question that intact D&E is a safe abortion procedure that may well be the safest procedure for some women in certain circumstances." 2003 Hearings, *supra*, at 191-195. Dr. J. Courtland Robinson stated that "sometimes it is necessary to deliver the fetus intact to perform the safest method of abortion." *Carhart* Pet. App. 69a. And Dr. Samuel Edwin stated that intact D&E "is the safest option for many women faced with medical emergencies during pregnancy," 141 Cong. Rec. S18192 (daily ed. Dec. 7, 1995) (statement of Sen. Levin). A chorus of other doctors echoed these statements.

Also squarely contradicted is Congress's finding that the intact variant actually harmed the health of women. Even the Government's experts conceded that there was no evidence to support Congress's finding that the intact variant increased the risk of "uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus." *See, e.g., PPFA* J.A. 727 (Shadigian Trial Test.); *id.* at 781 (Cook Trial Test.).

The medical evidence also fails to support Congress's finding that intact D&E increases a woman's risk of cervical incompetence, which can cause pre-term birth in subsequent pregnancies. *See Carhart* Pet. App. 594a-95a (Act § 2(14)(A)). Two different studies have found that dilation in a non-intact D&E procedure is not associated with cervical incompetence. *See* Kalish et al., *Impact of Mid-Trimester Dilation and Evacuation on Subsequent Pregnancy Outcome*, 187 Am. J. Obstetrics & Gynecology 882 (2002); Schneider et al., *Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation*, 88 Obstetrics & Gynecology 412 (1996). The dilation protocol is the same for both intact and non-intact procedures. Moreover, Dr. Chasen's follow-up study in 2005 concluded that, contrary to the findings of Congress and the testimony of some of the Government's witnesses, those who received intact D&E did not suffer higher rates of spontaneous, preterm

birth in future pregnancies. *See* Stephen T. Chasen et al., *Obstetric Outcomes After Surgical Abortion at ≥ 20 weeks' gestation*, 193 Am. J. Obstetrics & Gynecology 1161, 1163 (2005).

The Government's own witness perhaps best sums up the reliability of the congressional findings. Dr. Watson A. Bowes, Jr., who supports the ban and has never opposed any abortion restriction, testified at trial that had anyone in Congress sought his opinion, he would have advised Congress that the findings were inaccurate. *See PPFA* Pet. App. 195a. As Dr. Bowes stated, Congress's findings "cannot be supported by evidence-based medicine." CA8 App. 285.

## III. THE ACT WILL CHILL DOCTORS FROM PROVIDING SECOND-TRIMESTER ABORTIONS.

Because the Act is both vague and broad, it will chill doctors from providing a wide range of procedures used to perform induced abortions or to treat cases of miscarriage. This chill will extend well beyond those procedures that the Act purports to target.

First, the terms of the Act are ambiguous and foreign to the actual practice of medicine. As Dr. Carolyn Westhoff of Columbia testified at trial in *National Abortion Federation v. Ashcroft*,[6] another lawsuit challenging the constitutionality of the Act, "it's really difficult for me to tell when I am actually doing a case exactly whether I would be violating the ban." S.A. 11a. Confirming the validity of Dr. Westhoff's concerns, the Government's expert Dr. Lockwood conceded that before

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[6] 330 F. Supp. 2d 436 (S.D.N.Y. 2004), *aff'd*, 437 F.3d 278 (2d Cir. 2006).

speaking to "counsel for the government, [he] believed that the Act's language was so imprecise that it just doesn't prohibit intact D&Es but also threatens all abortions." *Id.* at 12a.

For one, "partial-birth abortion" is not a medical term: neither medical textbooks nor physicians use the term to define any particular procedure. *See 2003 Hearing*, *supra*, at 1. The Act exacerbates this problem by defining "partial-birth abortion" with terms that are themselves confusing. "Overt act," for example, could describe many of the steps that physicians take in any D&E or induction, such as severing the umbilical cord, separating a fetal part from the remainder, or compressing a part of the fetus that cannot otherwise pass through the cervix.

Moreover, though the Government asserts that the Act targets intact D&Es, the word "intact" does not appear in the Act. Remarkably, the Government has defended that omission on the grounds that including the word "intact" would create an "obvious loophole." S.A. 7a. Physicians cannot confidently treat their patients given these mixed signals.

This confusion is amplified by discrepancies between the Act's "Findings" and its operative language. For example, the Findings state that in a so-called partial-birth abortion, the physician "deliver[s] all but the head out of the womb." *Carhart* Pet. App. 597a (Act § 2(14)(J)). But to trigger the ban, the physician need deliver from the womb only "any part of the fetal trunk past the navel." *Id.* at 599a (Act § 3(a)). The Findings also refer to "converting" the fetus to a "breech position"; state that "labor is induced"; and describe "the doctor blindly forcing a sharp instrument into the base of the" fetal skull. *Id.* at 594a, 596a (Act § 2(14)(A) & (H)). But the ban includes no such elements, or anything like them. *See id.* at 599a

(Act § 3(a)). As one doctor explained, "I don't know if what is banned necessitates that I do those actions listed in the findings or not." S.A. 10a.

Second, the Act's scienter requirements only compound its vagueness. For example, the Act purports to target only procedures in which the physician delivers a certain portion of the fetus "for the purpose of performing an overt act the [physician] knows will kill the . . . fetus." *Carhart* Pet. App. 599a (Act § 3(a)). But the state-of-mind identified in the Act is not limited to intact D&Es. To the contrary, a physician begins a D&E with the intent of removing the fetus as intact as possible—but does not know whether intact removal will be possible or when fetal demise will occur.

Similarly, a physician begins every D&E intending to perform acts necessary to evacuate the uterus in a way that is safe for the woman. The physician also knows that such acts, which include cutting the umbilical cord or dismembering or compressing a fetal part, will result in fetal demise. Thus, in any D&E or induction procedure where part of the fetal trunk past the navel is outside the uterus, the physician will commit an "overt act" if necessary to complete the safe evacuation of the uterus.

As a result of these ambiguities, the Government's expert Dr. Lockwood testified that the Act could well be construed to "outlaw all D&Es." CA8 App. 489.[7] Even the Government essentially concedes that any D&E procedure might be covered by the Act. *Carhart* Pet'r. Br. 47 ("Where . . . a physician delivers . . . any part of the trunk past the navel . . . and then performs a discrete act that aborts the fetus, the procedure constitutes a 'partial-

[7] Another Government witness, Dr. Cook, recognized that Congress could have more narrowly tailored the Act to reach only intact D&E procedures. *See Carhart* Pet. App. 515a; CA8 App. 419-20.

birth abortion,' in the literal sense of the phrase, rather than a [non-intact D&E] regardless of whether the ultimate lethal act is . . . dismemberment.").

Indeed, when beginning any D&E, the physician knows that the safest way to proceed may well be to perform each of the steps in the Act's definition. *See Carhart* J.A. 52-53 (Doe Trial Test.), *id.* at 143 (Vibhakar Trial Test.), *id.* at 205-208 (Knorr Trial Test.). In every D&E and induction abortion, the physician "deliberately and intentionally" extracts the fetus from the uterus through the vaginal canal. *See Carhart* J.A. 108-09 (Fitzhugh Trial Test.). Likewise, the first time the physician inserts instruments into the woman's body, grasps part of the fetus, and withdraws the instrument, the physician may remove the fetus until part of the fetal trunk past the navel is outside the woman's body. Or, on the first pass with instruments, the physician may disjoin a leg from the rest of the fetus, and then, on the second pass, remove the fetus until part of the fetal trunk past the navel is outside the woman's body. In either of the previous two scenarios, these steps may occur—for a "living fetus" need not be intact. *See id.* at 109-11; *Carhart* Pet. App. 517a. Finally, in either scenario, if the remainder of the fetus within the uterus obstructs continued extraction, the physician would commit an "overt act," such as disjoining the part of the fetus outside the uterus, or compressing the fetal part that is obstructing delivery. In either scenario, that may occur before fetal demise.

The Act could also extend to inductions. For example, sometimes during an induction, the fetus is not fully expelled within a reasonable time, or the woman develops health complications (including hemorrhage and infection) before the procedure can be completed. In these situations, the physician must complete the fetal evacuation using instruments, and may violate the Act for

all the same reasons that a physician might violate the Act while performing a D&E. *See* Carhart J.A. 467-468 (Lockwood Trial Test.). In other instances, such as when the fetus has severe hydrocephalus, the fetal head is too large to pass through the woman's cervix. In this circumstance, the physician must reduce the size of the head to extract the fetus, and thus must perform an "overt act" that may kill the fetus. *See Carhart* J.A. 110-111 (Fitzhugh Trial Test.). One Government witness acknowledged that a doctor in that situation would face "the possibility of being charged." CA8 App. 363 (Sprang Trial Test.).

The Act's chilling effect is manifest. As Drs. Michael Greene and Jeffrey Ecker explained soon after the passage of the Act, physicians who performed non-intact D&Es feared "that the wording of the current bill is sufficiently imprecise that the procedures they are now doing could be construed to meet the criteria of the banned procedure." Michael Greene & Jeffrey Ecker, *Abortion, Health and the Law*, New Eng. J. Med. 350:2, Jan. 8, 2004, at 178. Dr. Paul Blumenthal similarly warned:

> None of my colleagues know or could state whether the abortion procedures they now perform are covered under this law. Indeed, as I read the definition of the banned procedures, any of the safest, most common abortion methods used throughout the second-trimester of pregnancy could proceed in such a manner as to be outlawed.

Paul Blumenthal, *The Federal Ban on So-Called "Partial-Birth Abortion" is a Dangerous Intrusion into Medical Practice*, Medscape Gen. Med., June 25, 2003, http://www.medscape.com/viewarticle/457581.

To so chill the provision of the only safe options for second-trimester abortion—D&E and induction—places an "undue burden" on the right to reproductive choice. It also gravely endangers the health of women in this country.

## IV. THE ACT WILL HINDER IMPROVEMENTS IN PATIENT SAFETY.

The Act also stifles physicians' ability to develop and vary techniques to increase safety for women. Such exploration and variation of known techniques led to the most common, safest abortion methods used today. *See Carhart* J.A. 163-164 (Howell Trial Test.). This Court has long recognized that "present medical knowledge" changes, *see City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 437 (1983), and that bans on abortion methods threaten to stymie medical advancement. Thus, in *Planned Parenthood v. Danforth*, the Court invalidated a broad ban on saline instillation because, among other things, the statute threatened to preclude "methods that may be developed in the future and that may prove highly effective and completely safe." 428 U.S. 52, 78 (1976). The Act at issue here also interferes with medical evolution and thus violates a guiding principle of this Court's prior abortion rulings.

For instance, physicians developed the vacuum-aspiration procedure as a safer alternative to dilatation and curettage ("D&C"), which was slower, less thorough, and caused more complications. *See* Pak Chung Ho, *Termination of Pregnancy Between 9 and 14 Weeks, in Modern Methods of Inducing Abortion* 54, 56-57 (David T. Baird et al. eds., 1995). Although vacuum aspiration had been described in medical literature for over a hundred years, it was not until abortion was legalized nationwide in 1973 that physicians were able to develop and perfect these techniques. *See Clinician's Guide*, *supra*, at 5-6,

107-08. Vacuum aspiration is now by far the most common method of first-trimester abortion. *See id.* It is also incredibly safe.

Later, the D&E procedure was developed when physicians experimented with ways to extend first-trimester surgical techniques to the second trimester. Physicians did so in the 1970s and 1980s, seeking an option safer than induction abortions, which were then the only method of second-trimester abortion short of abdominal surgery. In addition to requiring hospitalization, often over days, the induction method known at the time did not work before 16 weeks LMP. This meant that any woman past 12 weeks LMP had to wait—up to four weeks—until an induction was feasible. *See* Eugene Glick, *Surgical Abortion* 46-48 (1998).

Today, D&Es account for 95% of second-trimester abortions, and D&Es have essentially eclipsed inductions. Most of the credit for the rapid improvement in D&E techniques belongs to physicians who, over the years, have tested slightly varying techniques and have shared their discoveries with their colleagues. *See id.* And as this Court has recognized, the development of D&E was ultimately responsible for the remarkable improvements in the safety of post-first-trimester abortion that have occurred since *Roe*. *See Akron*, 462 U.S. at 435-37. One of the reasons D&E safety has itself improved so markedly is that physicians continue to innovate, using slightly varying techniques, and have taught the improved techniques to colleagues. *See, e.g.*, Glick, *supra*, at 47.

The growing prevalence of intact D&Es represents the continued evolution of the longstanding D&E method. Physicians have long recognized the safety advantages of minimizing the number of times they insert instruments into the patient's body, and physicians have long known

that intact extraction sometimes occurs. Through the intact variation, physicians simply try to increase the likelihood that this will occur for any given procedure, and they do this for one reason and one reason only: to minimize medical risk for their patients. *See Clinician's Guide*, *supra*, at 136.

If physicians are permitted to perform and improve the variant through clinical experience, these improvements may further advance medical knowledge and make abortion safer. If allowed to stand, the Act would stifle clinical progress, prevent further, peer-reviewed study of intact D&E, and cause immeasurable loss to women and their families.

## CONCLUSION

For the preceding reasons, the judgments of the Courts of Appeals should be affirmed.

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